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APPLICATION NO.	FILING DATE	INVENTOR NAME (LAST, FIRST, MIDDLE)	ATTORNEY NAME	ADDRESS
09/835,912	04/13/2001	David R. Goodlett	JOHN J. SHERIDAN	1000

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EXAMINER

MAHEWAN, CHANNING

ARTICLE 17

DATE

DATE MAILED 04/08/2003

Please find below and or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/835,072

Applicant(s)

GOODLETT ET AL

Examiner

Channing S. Mahatan

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 30-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 Sheet 6) ☐ Other:

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DETAILED ACTION*APPLICANTS' ARGUMENTS*

Applicants' arguments in Paper No. 9, filed 28 January 2003, have been fully considered but they are not deemed to be persuasive for the reasons set forth below. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Additionally, the species election requirement set forth in Paper No. 5, mailed 26 July 2002 is vacated, thus subject matter directed to internal amino acid residue, terminal amino acid residue, terminal and internal amino acid residue, amino acids post-translation modification, and amino acids without modifications are under examination. Claims 30-55 remains withdrawn from examination as not directed to the elected invention and/or subject matter.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-29.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required

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include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

SCOPE OF ENABLEMENT

Claims 1-29 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the disclosed method of determining amino acid sequence of a polypeptide (page 68-69), does not reasonably provide enablement for the determination of an amino acid sequence of a polypeptide by any other means. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification indicates the derivation of a polypeptide sequence by graphical representation from a pair of doubly charged CID spectra of d0- and d3-methyl-esterified peptides by the following steps: 1) filter low intensity peaks from both input spectra to reduce noise; 2) where integer values of n range from 1 to N create a node with mass (m) and number of methyl esters (n) if peaks are with m in the d0 spectrum and mass $m + n\delta \pm \epsilon$ in the d3 spectrum; 3) assign the created node an intensity value equal to the product of the intensities of the 2 peaks; 4) create a single source node with $m = M$ and $n = N$, and a single terminus node with $m = 0$ and $n = 1$; 5) add a labeled weighted directed edge from node 1 (m_1, n_1) is added to node 2 (m_2, n_2) if the edges if $m_1 = m_2 + \text{mass}$ [non-

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methyated amino acid(s)] $\pm \epsilon$ and $n_1 = n_2$ or $m_1 = m_2 + \text{mass}$ [aspartic or glutamic acid methyl ester] $\pm \epsilon$ and $n_1 = n_2 + 1$; 6) a label, corresponding to the satisfying amino acid(s) and a weight equal to the product of the two node intensities, is assigned to the edge; 7) the highest scoring path through the graph from the source node to the terminus node is derive from the score of a path computed as the sum of the weights of its edges; 8) the sequence of the polypeptide is given by (from carboxyl to amino-terminus) the labels of the edges of the highest scoring path (pages 68-69 of the Specification). However, the specification fails to provide for other means by which to determine amino acid sequence of a polypeptide. No other methods of determining amino acid sequence of a polypeptide are disclosed. None appear to have been known in the art. No guidance, direction, or examples are provided such that one of ordinary skill in the art would have known practice to use the claimed invention.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

VAGUE AND INDEFINITE

Claims 1-29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (lines 1-2) and all claims dependent therefrom are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states "A method of determining amino acid sequence of a polypeptide...", however the claim recites a final step "adding a labeled weighted directed

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edge...". The final step fails to indicate the determination of an amino acid sequence of a polypeptide. While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claim 2 (lines 3-6) and all claims dependent therefrom recites "further comprising" steps that are confusing. Particularly, the additionally steps are delineated as (a) and (b) wherein claim 2 depends from claim 1 which contains steps (a) and (b). Such presentation of additional steps is confusing as to the order in which they are to be performed. Clarification of the claim language is requested.

OBJECTION OF DISCLOSURE

The disclosure is objected to because of the following informalities (previously cited in Paper No. 7, mailed 22 October 2002:

The specification is objected to because of a typographical/spelling error: "plypeptide" should be replaced with "polypeptide" (page 5, line 22).

Appropriate Correction Is Required.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

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1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CMI Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

April 4, 2003

Examiner Initials:

CSM

Marianne P. Allen
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